Commissioner for the Department for Medicaid Services Selections for Preferred Products

This is a summary of the final Preferred Drug List (PDL) selections made by the Commissioner for the Department for Medicaid Services based on the Drug Review and Options for Consideration prepared for submittal to the Pharmacy and Therapeutics (P&T) Advisory Committee for review on November 19, 2015.

New Products to Market

Rexulti® will be placed non-preferred with similar quantity limits in the PDL class titled Second-Generation Antipsychotics.

Second-Generation Antipsychotics	Abilify® tablets CC, QL	*aripiprazole tablets QL*
	aripiprazole ODT, solution CC, QL	*Clozaril® QL*
	clozapine CC, QL	*FazaClo® QL*
	clozapine ODT CC, QL	*Geodon® QL*
	Fanapt™ CC, QL	*Invega® QL*
	Latuda® CC, QL	*paliperidone QL*
	olanzapine CC, QL	*Rexulti® QL*
	quetiapine CC, QL	*Risperdal® QL*
	risperidone CC, QL	*Seroquel® QL*
	Saphris® CC, QL	*Versacloz® QL*
	Seroquel® XR CC, QL	*Zyprexa® QL*
	ziprasidone CC, QL	

Daklinza™ will be Preferred in the Hep C agents class with the following PA criteria:

- Approve daclatasvir (Daklinza™) if ALL of the following are true:
  - Age ≥ 18 years; AND
  - Must be prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist; AND
  - Patient is treatment-naïve to all daclatasvir therapy. Limited to one course of therapy per lifetime.; AND
  - Patient is NOT taking any of the following contraindicated medications: phenytoin, carbamazepine, rifampin, and St. John's wort; AND
  - Patient is NOT receiving concomitant therapy with a hepatitis C protease inhibitor (e.g., telaprevir [Incivek], boceprevir [Victrelis], simeprevir [Olysio]; AND
  - Patient does NOT have a diagnosis of HCV genotypes 1, 2, 4, 5, or 6; AND
  - Patient has not actively participated in illicit substance abuse or alcohol abuse for 6 months prior to or during therapy attested by the prescribing physician(s) AND using one of the following confirmation tests administered both randomly and periodically throughout treatment:
    - Patient has been evaluated for current substance abuse and alcohol with validated screening instruments such as Alcohol Use Disorders Identification Test (AUDIT C) or CAGE alcohol screen, or National Institute on Drug Abuse's (NIDA's) drug screening tool; OR
    - Acceptable alcohol consumption tests include: Serum gamma-glutamyl transpeptidase (GGT), mean corpuscular volume (MCV), carbohydrate-deficient transferrin (CDT), and urine ethylglucuronide (EtG) tests. Results must be documented in the patient's medical record to include, results of testing, and date tested; AND
    - Urine toxicology screen results for substance abuse are acceptable in lieu of the actual laboratory drug screen report. Results must be documented in the patient's medical record to include substances tested, results of testing, and date tested; AND
  - If patient has a prior history of substance or alcohol abuse, within the past 6 months, the patient has completed or is participating in a recovery program, or receiving substance or alcohol abuse counseling services, or seeing an addiction specialist as part of HCV treatment; AND
  - Baseline HCV-RNA is submitted. HCV RNA level will be required at treatment week 4 for renewal; AND

- Have documentation of Disease Severity AND/OR Highest Risk for Disease Progression, defined as:
  - Disease Severity (patient MUST have one of the following):
    - Liver biopsy showing Metavir score of F2-F4; **OR**
    - Ultrasound based transient elastography (Fibroscan) score ≥ 7.1 kPa; OR
    - Evidence of any TWO of the following:
      - Fibrotest (FibroSure) score of ≥ 0.49
      - Fibrosis-4 index (FIB-4) > 3.25
      - Aspartate aminotransferase/platelet ratio index (APRI) score of > 0.5
      - Cirrhotic features on imaging
      - Physical exam consistent with cirrhosis; AND/OR
  - Documentation showing patient at the highest risk for severe complications (patient MUST have one of the following):
    - Advanced fibrosis (Metavir F3) or compensated cirrhosis (Metavir F4); OR
    - Essential mixed cryoglobulinemia with end organ manifestations (including arthralgias, palpable purpura, peripheral neuropathy, central nervous system vasculitis); OR
    - Proteinuria; OR
    - Nephrotic Syndrome; OR
    - Membranoproliferative glomerulonephritis; AND
- One of the following diagnoses:
  - For a diagnosis of chronic HCV genotype 3 without cirrhosis (Metavir F2-F3) approve for an initial 8 weeks of therapy IF patient meets ALL of the following criteria:
    - Used in combination with sofosbuvir 400mg daily; and
    - Approve initially:
      - A dose of 90 mg daily will be approved if the patient is taking a moderate CYP3A inducer (e.g., bosentan, dexamethasone, efavirenz, etravirine, modafinil, nafcillin, rifapentine).
      - A dose of 30 mg daily will be approved if the patient is taking a strong CYP3A inhibitor (e.g., atazanavir/ritonavir, clarithromycin, indinavir, itraconazole, ketoconazole, nefazodone, nelfinavir, posaconazole, saquinavir, telithromycin, voriconazole).
    - Approve for an additional 4 weeks (12 weeks total) of therapy (Authorization #2) IF patient meets ALL of the following criteria:
      - The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); AND

- If patient has a recent prior history, within the past 6 months, of substance or alcohol abuse, the patient is not actively participating in illicit substance abuse or alcohol abuse during therapy attested by the prescribing physician(s) AND using the same verification documentation listed for original authorization; AND
- HCV RNA levels are < 25 IU/mL at treatment week 4 (TW4).

- For a diagnosis of chronic HCV genotype 3 with cirrhosis (Metavir F4) approve for an initial 8 weeks of therapy IF patient meets ALL of the following criteria:
  - Used in combination with sofosbuvir 400mg daily; and
  - Treatment-naïve versus experienced:
    - Treatment-naïve patients must try and fail therapy sofosbuvir + ribavirin + pegylated interferon for 12 weeks OR sofosbuvir + ribavirin for 24 weeks.; or
    - Treatment-experienced patients must have tried and failed sofosbuvir + ribavirin + pegylated interferon OR be interferon ineligible; and
  - Approve initially:
    - A dose of 90 mg daily will be approved if the patient is taking a moderate CYP3A inducer (e.g., bosentan, dexamethasone, efavirenz, etravirine, modafinil, nafcillin, rifapentine).
    - A dose of 30 mg daily will be approved if the patient is taking a strong CYP3A inhibitor (e.g., atazanavir/ritonavir, clarithromycin, indinavir, itraconazole, ketoconazole, nefazodone, nelfinavir, posaconazole, saquinavir, telithromycin, voriconazole).
  - Approve for an additional 4 weeks (12 weeks total) of therapy (Authorization #2) IF patient meets ALL of the following criteria:
    - The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); AND
    - If patient has a recent prior history, within the past 6 months, of substance or alcohol abuse, the patient is not actively participating in illicit substance abuse or alcohol abuse during therapy attested by the prescribing physician(s) AND using the same verification documentation listed for original authorization; AND
    - HCV RNA levels are < 25 IU/mL at treatment week 4 (TW4).

Technivie™ will be preferred in the PDL class titled Hep C agents with the following PA criteria:

- Approved if ALL of the following criteria are met:
  - Age > 18 years; AND
  - Must be prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist; AND
  - Patient is NOT taking any of the following contraindicated medications: alfuzosin, carbamazepine, phenytoin, phenobarbital, rifampin, ergotamine, dihydroergotamine, ergonovine, methylergonovine, ethinyl estradiol-containing medications such as combined oral contraceptives, St. John's wart, lovastatin, simvastatin, pimozide, efavirenz, and sildenafil (when dosed as Revatio® for the treatment of pulmonary arterial hypertension), triazolam, and orally administered midazolam; AND
  - Patient is NOT receiving concomitant therapy with a hepatitis C protease inhibitor (e.g., telaprevir [Incivek], boceprevir [Victrelis], simeprevir [Olysio]; AND
  - Patient does NOT have a diagnosis of HCV genotypes 1, 2, 3, 5, or 6; AND
  - Patient does NOT have a cirrhosis; AND
  - Patient has not actively participated in illicit substance abuse or alcohol abuse for 6 months prior to or during therapy attested by the prescribing physician(s) AND using one of the following confirmation tests administered both randomly and periodically throughout treatment:
    - Patient has been evaluated for current substance abuse and alcohol with validated screening instruments such as Alcohol Use Disorders Identification Test (AUDIT C) or CAGE alcohol screen, or National Institute on Drug Abuse's (NIDA's) drug screening tool; OR
      - Acceptable alcohol consumption tests include: Serum gamma-glutamyl transpeptidase (GGT), mean corpuscular volume (MCV), carbohydrate-deficient transferrin (CDT), and urine ethylglucuronide (EtG) tests. Results must be documented in the patient's medical record to include, results of testing, and date tested; AND
      - Urine toxicology screen results for substance abuse are acceptable in lieu of the actual laboratory drug screen report. Results must be documented in the patient's medical record to include substances tested, results of testing, and date tested; AND
  - If patient has a prior history of substance or alcohol abuse, within the past 6 month, the patient has completed or is participating in a recovery program, or receiving substance or alcohol abuse counseling services, or seeing an addiction specialist as part of HCV treatment; AND
  - Baseline HCV-RNA is submitted. HCV RNA level will be required at treatment week 4 for renewal; AND

- Have documentation of Disease Severity AND/OR Highest Risk for Disease Progression, defined as:
  - Disease Severity (patient MUST have one of the following):
    - Liver biopsy showing Metavir score of F2-F3; OR
    - Ultrasound based transient elastography (Fibroscan) score ≥ 7.1 kPa; OR
    - Evidence of any TWO of the following:
      - Fibrotest (FibroSure) score of ≥ 0.49
      - Fibrosis-4 index (FIB-4) > 3.25
      - Aspartate aminotransferase/platelet ratio index (APRI) score of > 0.5; AND/OR
  - Documentation showing patient at the highest risk for severe complications (patient MUST have one of the following):
    - Essential mixed cryoglobulinemia with end organ manifestations (including arthralgias, palpable purpura, peripheral neuropathy, central nervous system vasculitis); OR
    - Proteinuria; OR
    - Nephrotic Syndrome; OR
    - Membranoproliferative glomerulonephritis; AND
- Diagnosis of chronic HCV genotype 4 without cirrhosis (without Metavir F4) approve for an initial 8 weeks of therapy IF patient meets ALL of the following criteria:
  - Used in combination with weight-based ribavirin (unless patient is treatment-naïve and cannot tolerate ribavirin).
  - Approve for an additional 4 weeks (12 weeks total) of therapy (Authorization #2) IF patient meets ALL of the following criteria:
    - The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); AND
    - If patient has a recent prior history, within the past 6 months, of substance or alcohol abuse, the patient is not actively participating in illicit substance abuse or alcohol abuse during therapy attested by the prescribing physician(s) AND using the same verification documentation listed for original authorization; AND
    - HCV RNA levels are < 25 IU/mL at treatment week 4 (TW4).

Of Note: Ombitasvir/ paritaprevir/ ritonavir (Technivie™) will be limited to one course of therapy per lifetime.

Hepatitis C: Direct-Acting Antiviral Agents	Viekira Pak® CC, QL	*Harvoni® CC, QL*
	Daklinza™ CC QL	*Olysio™ CC, QL*
	Technivie™ CC QL	*Sovaldi™ CC, QL*

Praluent® will be non-preferred in the PCSK9 Inhibitors class with the following PA criteria:

- Approve alirocumab (Praluent®) if ALL of the following criteria are met:
- For initial therapy (initial 3 months):
  - Patient has a diagnosis of atherosclerotic cardiovascular disease (ASCVD) or heterozygous familial hypercholesterolemia (HeFH) as confirmed by genotyping or by clinical criteria ("definite FH" using either the Simon Broome or WHO/Dutch Lipid Network criteria); AND
  - Patient age ≥ 18 years; AND
  - Request is from or in consultation with a specialist (including cardiologists, lipidologists, or endocrinologists); AND
  - Patient has tried and failed highest available dose or maximally-tolerated dose of high intensity statin (atorvastatin or rosuvastatin) AND ezetimibe for at least three continuous months with failure to reach target LDL-C (70 mg/dL for patients with clinical ASCVD and 100 mg/dL for patients with HeFH and no history of clinical ASCVD).
    - If the patient failed to reach target LDL-C (<70 mg/dL for patients with clinical ASCVD and <100 mg/dL for patients with HeFH and no history of clinical ASCVD), adherence to maximally-tolerated statin and ezetimibe has been verified using pharmacy claims data and the patient is determined to be compliant for at least three consecutive months prior to the lipid panel demonstrating suboptimal reduction; or
    - If the patient is not able to use a maximum dose of atorvastatin or rosuvastatin due to muscle symptoms, documentation of a causal relationship must be established between statin use and muscle symptoms.
      - Documentation must demonstrate that the patient experienced pain, tenderness, stiffness, cramping, weakness, and/or fatigue and all of the following:
        - Muscle symptoms resolve after discontinuation of statin; and
        - Muscle symptoms occurred when rechallenged at a lower dose of the same statin; and
        - Muscle symptoms occurred after switching to an alternative statin; and
        - Documentation ruling out non-statin causes of muscle symptoms (e.g., hypothyroidism, reduced renal function, reduced hepatic function, rheumatologic disorders, such as polymyalgia rheumatica, steroid myopathy, vitamin D deficiency, or primary muscle disease); or
      - The patient has been diagnosed with statin-induced rhabdomyolysis
        - The diagnosis should be supported by acute neuromuscular illness or dark urine AND an acute elevation in creatine kinase (usually >5,000 IU/L or five times the upper limit of normal); AND

  - Maximally-tolerated statin will continue to be used; AND
  - Patient has not had a prior trial and failure of an alternative PCSK9 inhibitor; AND
  - Request is being made for the lowest approved dose to adequately treat the patient. Requests for an escalated dose must contain a lipid panel documenting suboptimal reduction in LDL-C after at least 4 weeks of the lower dose.
- For continuation of therapy:
  - Lipid panel showing a further reduction in LDL-C compared to the labs prior to initiating therapy; AND
  - Continued adherence to maximally-tolerated statin dose established prior to the original approval.

Repatha™ will be non-preferred in the PCSK9 Inhibitors class with the following PA criteria:

- Approve evolocumab (Repatha™) if ALL of the following criteria are met:
  - For initial therapy (initial 3 months):
    - Patient has a diagnosis of:
      - Atherosclerotic cardiovascular disease (ASCVD) or heterozygous familial hypercholesterolemia (HeFH) as confirmed by genotyping or by clinical criteria ("definite FH" using either the Simon Broome or WHO/Dutch Lipid Network criteria); or
      - Homozygous familial hypercholesterolemia (HoFH) as confirmed by either:
        - Documented DNA test for functional mutation(s) in both LDL receptor alleles or alleles known to affect LDL receptor functionality; or
        - A history of an untreated LDL-C concentration > 500 mg/dL and triglycerides <300 mg/dL and both parents with documented untreated TC >250 mg/dL; AND
    - Patient age ≥ 18 years if diagnosis is atherosclerotic cardiovascular disease (ASCVD) or heterozygous familial hypercholesterolemia (HeFH) or ≥ 13 years if diagnosed with homozygous familial hypercholesterolemia (HoFH); AND
    - Request is from or in consultation with a specialist (including cardiologists, lipidologists, or endocrinologists); AND
    - Patient has tried and failed highest available dose or maximally-tolerated dose of high intensity statin (atorvastatin or rosuvastatin) AND ezetimibe for at least three continuous months with failure to reach target LDL-C (70 mg/dL for patients with clinical ASCVD and 100 mg/dL for patients with HeFH and no history of clinical ASCVD).
      - If the patient failed to reach target LDL-C (<70 mg/dL for patients with clinical ASCVD and <100 mg/dL for patients with HeFH or HoFH and no history of clinical ASCVD), adherence to maximally-tolerated statin and ezetimibe has been verified using pharmacy claims data and the patient is

determined to be compliant for at least three consecutive months prior to the lipid panel demonstrating suboptimal reduction; or

- If the patient is not able to use a maximum dose of atorvastatin or rosuvastatin due to muscle symptoms, documentation of a causal relationship must be established between statin use and muscle symptoms.
  - Documentation must demonstrate that the patient experienced pain, tenderness, stiffness, cramping, weakness, and/or fatigue and all of the following:
    - Muscle symptoms resolve after discontinuation of statin; and
    - Muscle symptoms occurred when rechallenged at a lower dose of the same statin; and
    - Muscle symptoms occurred after switching to an alternative statin; and
    - Documentation ruling out non-statin causes of muscle symptoms (e.g., hypothyroidism, reduced renal function, reduced hepatic function, rheumatologic disorders, such as polymyalgia rheumatica, steroid myopathy, vitamin D deficiency, or primary muscle disease); or
  - The patient has been diagnosed with statin-induced rhabdomyolysis
    - The diagnosis should be supported by acute neuromuscular illness or dark urine AND an acute elevation in creatine kinase (usually >5,000 IU/L or five times the upper limit of normal); AND
- Maximally-tolerated statin will continue to be used; AND
- Patient has not had a prior trial and failure of an alternative PCSK9 inhibitor.

- For continuation of therapy:
  - Lipid panel showing a further reduction in LDL-C compared to the labs prior to initiating therapy; AND
  - Continued adherence to maximally-tolerated statin dose established prior to the original approval.

Lipotropics: PCSK9s Inhibitors	N/A	*Praluent® CC* *Repatha™ CC*

Synjardy® will be non-preferred in the SGLT2 Inhibitors class.

Diabetes: SGLT2 Inhibitors	Invokana® ST	*Farxiga™* *Invokamet™* *Jardiance®* *Synjardy®* *Xigduo™ XR*

Class Review & Criteria Reviews

Oral Oncology, Breast Cancer

1. DMS to select preferred agent(s) based on economic evaluation; however, at least palbociclib, tamoxifen, and one Aromatase Inhibitor should be preferred.
2. Continue quantity limits based on FDA-approved maximum dose.
3. Agents not selected as preferred will be considered non-preferred and require PA.
4. DMS to allow continuation of therapy for existing users of non-preferred single-source branded products via a 90 day look back.
5. For any new chemical entity in the Oral Oncology, Breast Cancer class, require a PA until reviewed by the P&T Advisory Committee.

Oral Oncology Agents, RCC, Breast and Prostate Cancer	Afinitor™ oral QL	*Afinitor Disperz™ QL*
	Anastrozole QL	*Arimidex® QL*
	Exemestane QL	*Aromasin® QL*
	Ibrance® QL	*Fareston® QL*
	Inlyta® CC, QL	*Faslodex® QL*
	Letrozole QL	*Femara QL*
	Nexavar® QL	*Votrient™ QL*
	Sutent® QL	*Xtandi® QL*
	Tamoxifen citrate QL	
	Tykerb® QL	
	Zytiga™ QL	

Antimigraine Agents

1. DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity should be preferred. At least one non-oral dosage form should be preferred.
2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization.
3. Agents in this class should have quantity limits based on the FDA-approved maximum dose and duration.
4. As part of quantity limit override criteria, patients should be on concurrent migraine prophylaxis therapy at a therapeutic dose.
5. For any new chemical entity in the Antimigraine Agents class, require a PA until reviewed by the P&T Advisory Committee.

Anti-Migraine: 5-HT1 Receptor Agonists	rizatriptan ODT QL rizatriptan QL Relpax™ QL sumatriptan QL	*almotriptan QL* *Alsuma™ QL* *Amerge® QL* *Axert® QL* *Cambia™ QL* *Frova™ QL* *Imitrex® QL* *Maxalt® QL* *Maxalt-MLT® QL* *naratriptan QL* *Sumavel™* *Dosepro™ QL* *Treximet™ QL* *Zecuity® QL* *zolmitriptan QL* *zolmitriptan ODT QL* *Zomig® QL* *Zomig-ZMT® QL*

Antiparkinson's Agents

Anticholinergics, Parkinson's Disease

1. DMS to select preferred agent (s) based on economic evaluation; however, at least benztropine should be preferred.
2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization.

For any new chemical entity in the Anticholinergics, Parkinson's disease class, require a PA until reviewed by the P&T Advisory Committee.

Dopamine Precursor / Dopa Decarboxylase Inhibitors

1. DMS to select preferred agent (s) based on economic evaluation; however, at least one product combining levodopa and carbidopa should be preferred.
2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization.

For any new chemical entity in the Dopamine Precursor/Dopa Decarboxylase Inhibitors class, require a PA until reviewed by the P&T Advisory Committee.

Monoamine Oxidase (MAO)-B Inhibitors

1. DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity should be preferred.
2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization.
3. For any new chemical entity in the Monoamine Oxidase (MAO)-B Inhibitors class, require a PA until reviewed by the P&T Advisory Committee.

Dopamine Receptor Agonists

1. DMS to select preferred agent (s) based on economic evaluation; however, at least two unique chemical entities should be preferred.
2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization.
3. For any new chemical entity in the Dopamine Receptor Agonists class, require a PA until reviewed by the P&T Advisory Committee.

Catechol-O-Methyltransferase (COMT) Inhibitors

1. DMS to select preferred agent (s) based on economic evaluation; however, at least entacapone should be preferred. Tolcapone can be considered an inferior product in this category due to potential liver toxicity; therefore, it should be non-preferred and require PA.
2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization.
3. For any new chemical entity in the Catechol-O-Methyltransferase (COMT) Inhibitors class, require a PA until reviewed by the P&T Advisory Committee.

Parkinson's Disease, Other

1. DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity should be preferred.
2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization.
3. For any new chemical entity in the Parkinson's disease, Other class, require a PA until reviewed by the P&T Advisory Committee.

Parkinson's Disease	amantadine syrup, tablets, capsules benztropine carbidopa Comtan® levodopa/carbidopa levodopa/carbidopa CR levodopa/carbidopa ODT selegiline tablets trihexyphenidyl	*Azilect®* *Duopa™* *entacapone* *levodopa/carbidopa/entacaone* *Lodosyn®* *Parcopa™* *Rytary™* *selegiline capsules* *Sinemet®* *Sinemet® CR* *Stalevo®* *Tasmar®* *tolcapone* *Zelapar™*

Sedative Hypnotics

1. DMS to select preferred agent(s) based on economic evaluation; however, at least four unique chemical entities should be preferred. One non-benzodiazepine sedative hypnotic should be among the preferred products.
2. Place quantity limits on agents in the category according to the FDA recommended maximum dose.
3. Agents not selected as preferred will be considered non-preferred and require PA.
4. For any new chemical entity in the Sedative Hypnotic class, require a PA and quantity limit until reviewed by the P&T Advisory Committee.

Sedative Hypnotic Agents	flurazepam QL temazepam 15 mg, 30 mg QL triazolam QL zolpidem QL	*Ambien® QL* *Ambien CR® QL* *Belsomra® QL* *Doral® QL* *Edluar® CC, QL* *estazolam QL* *eszopiclone QL* *Halcion® QL* *Hetlioz® CC, QL* *Intermezzo® QL* *Lunesta™ QL* *Restoril® QL* *Rozerem® CC, QL* *temazepam 22.5 mg, 7.5 mg QL* *Silenor® QL* *Somnote®* *Sonata® QL* *zaleplon QL* *zolpidem ER QL* *Zolpimist™ QL*

Zolpidem Sublingual / Oral Spray (Edluar® / Intermezzo® / Zolpimist™) Clinical Criteria

Zolpidem sublingual/ oral spray (Edluar®/Intermezzo®/Zolpimist™) approved if one of the following criteria are met:

- Diagnosis of dysphagia; OR
- Trial and failure of 2 preferred sedative hypnotics, one of which must be zolpidem.

Tasimelteon (Hetlioz®) Clinical Criteria

Tasimelteon (Hetlioz®) will be approved for a diagnosis of Non-24-hour sleep-wake disorder ("non-24") in patients who are totally blind.

Skeletal Muscle Relaxants

1. DMS to select preferred agent (s) based on economic evaluation; however, at least four unique chemical entities, two typically used for spasticity and two typically used as an antispasmodic, should be preferred. Carisoprodol can be considered an inferior product in this category due to abuse potential; therefore, it should be non-preferred and require PA.
2. Agents not selected as preferred will be considered non-preferred and require PA.
3. Continue current quantity limits on agents in this category based on FDA maximum recommended dose and duration.

For any new chemical entity in the Skeletal Muscle Relaxants class, require PA until reviewed by the P&T Advisory Committee.

Skeletal Muscle Relaxants	baclofen QL chlorzoxazone QL cyclobenzaprine QL methocarbamol QL orphenadrine QL orphenadrine compound QL orphenadrine compound forte QL tizanidine tablets QL	*Amrix® QL, MD* *carisoprodol QL, MD* *carisoprodol compound QL, MD* *cyclobenzaprine ER QL, MD* *Dantrium® QL* *dantrolene QL* *Fexmid® QL, MD* *Flexeril® QL, MD* *Lorzone® QL* *metaxalone QL* *methocarbamol/aspirin QL* *Parafon Forte DSC® QL* *Robaxin® QL* *Skelaxin® QL* *Soma® QL, MD* *tizanidine capsules QL* *Zanaflex® QL*

Dantrolene Clinical Criteria

Dantrolene will be approved for the follow diagnoses:

- Muscle spasticity after trial and failure, unless contraindicated, of TWO preferred Skeletal Muscle Relaxants; OR
- Prophylaxis against malignant hyperthermia.

Tobacco Cessation

1. DMS to select preferred agent(s) based on economic evaluation; however, at least three unique chemical entities should be preferred.
2. Agents not selected as preferred will be considered non-preferred and require PA.
3. Continue quantity limits on drugs in this class based on maximum FDA-approved dose.
4. For any new chemical entity in the Tobacco Cessation class, require a PA until reviewed by the P&T Advisory Committee.

Tobacco Cessation	bupropion SR QL Chantix® QL nicotine buccal/gum/lozenge QL nicotine transdermal system QL	*Commit®* QL *Habitrol®* QL *Nicoderm®* QL *Nicoderm CQ®* QL *Nicorelief®* QL *Nicorette®* QL *Nicotrol® Inhaler* QL *Nicotrol® NS* QL *Nicotrol® Patch* QL *Prostep®* QL *Zyban®* QL

Short-Acting Narcotic Analgesics

1. DMS to select preferred agent (s) based on economic evaluation; however, at least generic formulations of hydrocodone, hydromorphone, meperidine, morphine, and oxycodone should be preferred.
2. Agents not selected as preferred will be considered non-preferred and require PA.
3. For any new chemical entity in the Short-Acting Narcotic Analgesics class, require PA until reviewed by the P&T Advisory Committee.

Narcotics: Short-Acting	butalbital/APAP/caffeine CC codeine/APAP MD dihydrocodeine bitartrate/APAP/caffeine hydrocodone/APAP MD hydrocodone/ibuprofen hydromorphone liquid, tablets meperidine morphine IR oxycodone oxycodone/APAP MD tramadol	*All branded short-acting narcotics and narcotic combinations* *butalbital/APAP/caffeine/codeine CC* *butalbital compound/codeine CC* *codeine* *Capital®* *Demerol®* *dihydrocodeine bitartrate/ASA/caffeine* *Dilaudid®* *Endodan®* *Hycet®* *hydromorphone suppositories* *Ibudone™* *levorphanol* *Margesic H®* *Maxidone®* *Norco®* *Nucynta™* *Opana®* *Oxaydo®* *oxycodone/ASA MD* *oxycodone/ibuprofen* *oxymorphone IR* *Primlev®* *Reprexain™* *Rybix™ ODT* *Synalgos DC®* *tramadol APAP* *Trezix®* *Ultracet®* *Ultram®* *Vanatol™ LQ CC* *Xartemis™ XR* *Xodol®* *Xolox®* *Zamicet™* *Zolvit™*

Long-Acting Narcotic Analgesics

1. DMS to select preferred agent (s) based on economic evaluation; however, at least one long acting form of morphine and topical fentanyl should be preferred.
2. Agents not selected as preferred will be considered non-preferred and require PA.
3. For any new chemical entity in the Long-Acting Narcotic Analgesics class, require PA until reviewed by the P&T Advisory Committee.

Narcotics: Long-Acting	fentanyl transdermal 12, 25, 50, 75, 100 mcg CC, QL Kadian® QL morphine sulfate SA (Generic for MS Contin®) QL	*Avinza™ QL* *Butrans™ CC, QL* *ConZip™ QL* *Dolophine®* *Duragesic® CC, QL* *Embeda™ QL* *Exalgo™ QL* *fentanyl transdermal 37.5, 62.5, 87.5 mcg CC, QL* *hydromorphone ER QL* *Hysingla™ ER QL* *Ionsys® CC, QL* *morphine sulfate SA (Generic Kadian®, Avinza™) QL* *MS Contin® QL* *Nucynta® ER CC,QL* *Opana ER® QL* *Oramorph® SR QL* *oxycodone ER/SR QL* *OxyContin® QL* *oxymorphone ER QL* *Ryzolt™ QL* *tramadol ER QL* *Ultram® ER QL* *Zohydro ER™ CC,QL*

Fentanyl Transdermal Clinical Criteria

Fentanyl transdermal will be approved if all of the following are true:

- Diagnosis of chronic pain; AND
- Trial and failure of extended/controlled release morphine.

Buprenorphine Transdermal (Butrans™) Clinical Criteria

Buprenorphine transdermal (Butrans™) will be approved if all of the following are true:

- Diagnosis of chronic pain; AND
- Trial and failure of extended/controlled release morphine; AND
- Patient does not have a history of opioid addiction.

Hydrocodone Extended-Release Clinical Criteria

Hydrocodone extended-release (Hysingla™ ER/ Zohydro™ ER) will be approved if ALL of the following are true:

- Patients ≥18 years of age; AND
- Prescriber is a Pain Management Specialist or prescriber has proof of consultation with a Pain Management specialist; AND
- Diagnosis of severe pain requiring daily, around-the-clock, long-term pain management, defined as;
  - Pain lasting >6 consecutive months; AND
  - Trial and failure of one non-opioid analgesic (i.e., NSAIDs, APAP) at maximum tolerated doses without adequate relief of pain; AND
  - Trial and failure of one short-acting opioid analgesic at maximum tolerated doses without adequate relief of pain; **AND**
- Trial and failure of two preferred long-acting opioids; AND
- Patient does NOT have a history of drug or alcohol abuse/dependence or addiction(drug and alcohol toxicology screen results dated within the past month must be submitted with the PA request); AND
- If the patient is female between the ages of 18 and 45 years of age, prescriber must attest to the fact that patient has been counseled regarding the risks of becoming pregnant while on this medication, including the risk of neonatal abstinence syndrome (NAS); AND
- Patient does NOT have respiratory depression, acute or severe bronchial asthma, or hypercarbia; AND
- Patient does NOT have paralytic ileus.

Methadone Clinical Criteria

Methadone will be approved if all of the following are met:

- Request is from the prescriber; AND
- Diagnosis of:
  - Neonatal abstinence syndrome (NAS)
    - Will be approved for 30 days only in infants up to 1 year of age who are discharged from the hospital on a methadone taper; or
  - Pain:
    - Prescriber is a Pain Management Specialist or prescriber has proof of consultation with a Pain Management specialist; **AND**
    - Severe pain requiring daily, around-the-clock, long-term pain management, defined as;
      - Pain lasting >6 consecutive months; and
      - Trial and failure of one non-opioid analgesic (i.e., NSAIDs, APAP) at maximum tolerated doses without adequate relief of pain; and
      - Trial and failure of one short-acting opioid analgesic at maximum tolerated doses without adequate relief of pain; **AND**
    - Trial and failure of two preferred long-acting opioids; AND
    - Patient does NOT have a history of drug or alcohol abuse/dependence or addiction(drug and alcohol toxicology screen results dated within the past month must be submitted with the PA request); AND
    - If the patient is female between the ages of 18 and 45 years of age, prescriber must attest to the fact that patient has been counseled regarding the risks of becoming pregnant while on this medication, including the risk of neonatal abstinence syndrome (NAS); AND
    - Patient is not presently taking any other single entity immediate-release or extend-release opioids.
    - Note: Methadone will not be approved for drug addiction as a pharmacy benefit.

Tapentadol Extended-Release (Nucynta® ER) Clinical Criteria

Tapentadol extended-release (Nucynta® ER) will be authorized for the following diagnoses:

- Pain after trial and failure of one preferred product; OR
- Diabetic Peripheral Neuropathy after trial and failure of TWO of the following:
  - One SNRI; or
  - One anticonvulsant; or
  - One tricyclic antidepressant.

Fentanyl Buccal Products

1. DMS to select preferred agent (s) based on economic evaluation.
2. Require prior approval for all of these agents to ensure utilization based on FDA-approved indication.
3. For any new chemical entity in the Fentanyl Buccal Products class, require PA until reviewed by the P&T Advisory Committee.

Narcotics: Fentanyl Buccal Products	N/A	*Abstral®* CC, QL *Actiq®* CC, QL *fentanyl citrate lollipop* CC, QL *Fentora®* CC, QL *Lazanda®* CC, QL *Onsolis™* CC, QL *Subsys®* CC, QL

Fentanyl Buccal Products Clinical Criteria

Fentanyl Buccal products will be approved if ALL of the following are true:

- Diagnosis of cancer pain unresponsive to any other therapy; AND
- Receiving and tolerant to opioid therapy, as evident by trial of opioid doses equal to, or greater than, morphine 60 mg daily or fentanyl patches 50 mcg/hr for at least one week without adequate pain control; AND
- Patient must have tried and failed or had a contraindication to or intolerance to the generic equivalent before obtaining approval for the branded agent.
- These requests must be submitted on the Brand Medically Necessary Form.

Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

1. DMS to select preferred agent(s) based upon economic evaluation; however, at least six unique chemical entities should be preferred.
2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization.
3. Any new chemical entity in the Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) class should require a PA until reviewed by the P&T Advisory Committee.

Non-Steroidal Anti-Inflammatory Drugs	celecoxib QL diclofenac sodium flurbiprofen ibuprofen indomethacin ketoprofen ketorolac tromethamine QL meloxicam tablets naproxen tablets piroxicam sulindac	*Anaprox®* *Anaprox® DS* *Ansaid®* *Arthrotec®* *Cataflam®* *Celebrex® QL* *Clinoril®* *Daypro®* *Dermacin RX Lexitral PharmaPak®* *diclofenac/misoprostol* *diclofenac potassium* *diclofenac topical* *diclofenac SR* *diflunisal* *Duexis® CC* *etodolac* *etodolac SR* *Feldene®* *fenoprofen* *Flector® CC* *Indocin®* *indomethacin ER* *ketoprofen ER* *meclofenamate* *mefenamic acid* *meloxicam suspension* *Mobic®* *nabumetone* *Nalfon®* *Naprelan® EC* *naproxen sodium* *naproxen suspension* *naproxen CR* *naproxen EC* *oxaprozin* *Pennsaid® CC* *Pennsaid® Pump CC* *Ponstel®* *Sprix™ CC* *Tivorbex®* *tolmetin* *Vimovo™ QL* *Voltaren® Gel CC* *Voltaren® XR* *Zipsor™* *Zorvolex™*

Combination Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) Clinical Criteria

Esomeprazole/naproxen (Vimovo®) or ibuprofen/famotidine (Duexis®) will only be approved for patients who cannot take the individual components of the requested product.

Topical Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) Clinical Criteria

Topical non-steroidal anti-inflammatory drugs (NSAIDs) will be approved if one of the following is true:

- Patient is unable to tolerate, swallow, or absorb oral NSAIDS; OR
- Contraindication to oral NSAID (e.g., active GI bleed); OR
- Patient has tried 2 preferred oral NSAID agents.